

§ 20.24

(b) Records or documents prepared by the Food and Drug Administration for routine public distribution, e.g., pamphlets, speeches, and educational materials, shall be furnished free of charge upon request as long as the supply lasts. The provisions of this part shall not be applicable to such requests except when the supply of such material is exhausted and it is necessary to reproduce individual copies upon specific request.

(c) All existing Food and Drug Administration records are subject to routine destruction according to standard record retention schedules.

§ 20.24 Preparation of new records.

(a) The Freedom of Information Act and the provisions of this part apply only to existing records that are reasonably described in a request filed with the Food and Drug Administration pursuant to the procedures established in subpart C of this part.

(b) The Commissioner may, in his discretion, prepare new records in order to respond adequately to a request for information when he concludes that it is in the public interest and promotes the objectives of the act and the agency.

§ 20.25 Retroactive application of regulations.

The provisions of this part apply to all records in Food and Drug Administration files.

§ 20.26 Indexes of certain records.

(a) Indexes shall be maintained, and revised at least quarterly, for the following Food and Drug Administration records:

(1) Final orders published in the FEDERAL REGISTER with respect to every denial or withdrawal of approval of a new drug application or a new animal drug application for which a public hearing has been requested.

(2) Statements of policy and interpretation adopted by the agency and still in force and not published in the FEDERAL REGISTER.

(3) Administrative staff manuals and instructions to staff that affect a member of the public.

(4) Records that have been released to any person in response to a Freedom

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of Information request and that the agency has determined have become, or are likely to become, the subject of subsequent requests for substantially the same records.

(b) Each such index will be made available through the Internet at <http://www.fda.gov>. A printed copy of each index is available by writing to the Freedom of Information Staff (HF1-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, or by visiting the Freedom of Information Public Reading Room in rm. 12A-30 at the same address.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 68 FR 25285, May 12, 2003]

§ 20.27 Submission of records marked as confidential.

Marking records submitted to the Food and Drug Administration as confidential, or with any other similar term, raises no obligation by the Food and Drug Administration to regard such records as confidential, to return them to the person who has submitted them, to withhold them from disclosure to the public, or to advise the person submitting them when a request for their public disclosure is received or when they are in fact disclosed.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.28 Food and Drug Administration determinations of confidentiality.

A determination that data or information submitted to the Food and Drug Administration will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.29 Prohibition on withdrawal of records from Food and Drug Administration files.

No person may withdraw records submitted to the Food and Drug Administration. All Food and Drug Administration records shall be retained by the